

March 2016

URGENT PRODUCT RECALL
BD Retic-Count™ Reticulocyte Reagent System (IVD)
Catalog Number: 349204
Lot Number 5175559 (expires 05-31-2016)

Dear Valued Customer:

BD has determined that the box artwork for the lot referenced above contains an error. Discard all remaining stock of affected lot in your inventory and request replacement product. Examine your data files obtained using reagents from the affected lot for low performance.

Problem Description and Health Risk

The BD Retic-Count reticulocyte reagent system box artwork was found to incorrectly state the storage condition of 2°C –25°C (see Figure 1). The correct storage condition is 2°C –8°C. The labels on the reagent as well as the accompanying Instructions for Use are correct. The likelihood of occurrence of harm resulting from this defect is low.

Figure 1: Example Label



Customer Actions

1. Examine your data files obtained using reagents from the affected lots for low performance.
2. Discard all remaining stock of BD Retic-Count™ reticulocyte reagent system, Catalog Number 349204, lot number 5175559, and request replacement product. BD will replace product at no cost.
3. As a requirement of our Regulatory Tracking Process, we request that you complete the enclosed Tracking/Verification form, even if you no longer have the affected reagents listed in your inventory. Please return the Tracking/Verification form to BD Biosciences, per the instructions (mail, fax, or email).

If you require further assistance, please contact BD Customer Support at 877.232.8995 (prompt 3, 3) in the United States. For customers outside the US, contact your local BD Biosciences representative or distributor.

Please accept our apology for the inconvenience this may cause. BD is committed to providing you with high-quality products. Thank you for your continued support.

Sincerely,

Melissa Quinn
Manager Regulatory Compliance
BD Biosciences

BD Biosciences

Verification Form/Effectiveness Check

PLEASE FILL OUT AND RETURN

**Mail: BD Biosciences
Attn: Quality Assurance
2350 Qume Drive
San Jose, CA 95131**

Email: BDSJ_PIR @BD.COM

Fax: 408.577.1409

We do not have any of the following stock on hand.

We have the following units and request replacements:

BD Retic-Count™ reticulocyte reagent system (IVD)

Catalog Number: 349204

Lot Number 5175559 (expires 05-31-2016) - Quantity: _____

I have read and understood the attached notice.

Name: _____

Title: _____

Signature/Date: _____

COMPANY NAME: _____

ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

PHONE NO. _____